



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service ^{D1350 B}
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502
Telephone (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 22, 1997

Our Reference No.: 29-53673

Bahira Sells, Owner
Le Patisserie
1945 East Francisco Blvd.
San Rafael, CA 94901

WARNING LETTER

Dear Ms. Sells:

On December 17, 1997, FDA Investigator Lorna F. Jones conducted an inspection of your bakery facility, which will be providing baked food items to airline caterers and [REDACTED]. Your operations are in serious violation of the federal regulations for good manufacturing practices (GMP's) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110), Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. Observations by FDA Investigator Jones were listed on Form FDA 483, and discussed with Gilbert E. Sells, General Manager, at the conclusion of the inspection.

Lack of adequate food protection was demonstrated by the following observations: Packages of raw chicken were stored directly above the rolls of buche de noel; there were no sanitizers used for washing the sheet pans and the utensils; the bread trays are washed and rinsed directly on the cement pavement; there are no backflow prevention devices attached to the potable water lines used for cleaning and washing bread trays and the processing floor; soiled wiping cloths, containing dirt and grease build-up, were stored next to clean sheet pans and utensils; handles of knives used to slice dough were covered with dirty duct tape; live birds were observed eating dough residues inside the firm's production area.

These insanitary conditions are likely to result in adulteration of foods within the meaning of Sections 402(a)(3) and/or 402(a)(4) of the Food, Drug and Cosmetic Act. Adulteration of food while held for sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act. Delivery or causing the delivery of adulterated foods into interstate commerce is prohibited by Section 301(a).

The findings were discussed with Gilbert E. Sells, General Manager, at the conclusion of the inspection, and copies of FDA 483, List of Observations, were provided to him. Copies of FDA 483, List of Observations, and Form FDA 2420, Food Service Establishment Inspection Report, are being provided to you for your information.

Based on these findings, your facilities have been assessed a "Provisional" classification. A "Provisional" classification means that if the deficiencies are not corrected within thirty working days from receipt of this notification, your firm will be placed on "Not Approved" status. A "Not Approved" status means that food and beverage will be prohibited from use by interstate conveyances at the San Francisco International Airport.

Failure to take prompt corrective action may result in appropriate regulatory action, such as seizure and/or injunction without further notice. You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. If corrective action cannot be completed within fifteen working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to:

Randall P. Zielinski, CSO/ITS
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Charles D. Mass
Acting District Director

for

Patricia C. Ziobro
District Director
San Francisco District

cc:

[REDACTED]

[REDACTED]